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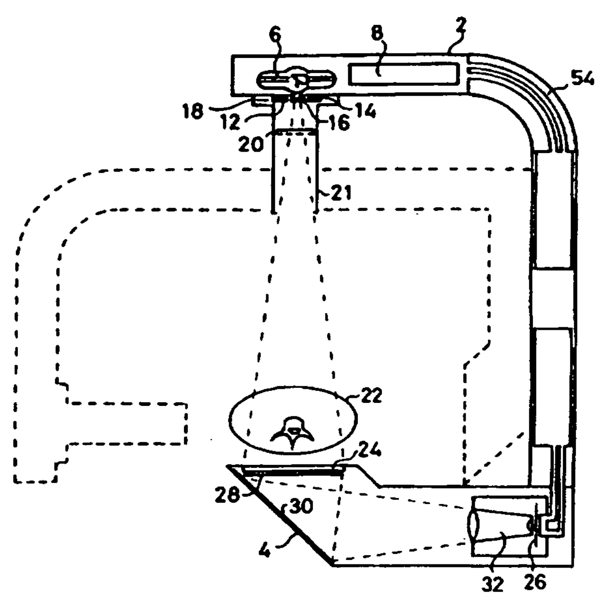

(57) Abstract

A method and a system for generating an X-ray image based on two irradiations of an object using two different X-ray radiation spectra in order to be able to e.g. perform a background correction and to enhance given features in the image. According to the invention, to generate the two intensity profiles, the X-ray radiation emitted by an X-ray source (6) is filtered using two K-shell filters (20) (one for each spectrum). Therefore, the present system is a stable and more shockproof system. The present system and method may be used for generating images for diagnostic purposes or for forming the basis of e.g. BMD/BMC calculations of bone structures in the image.

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A METHOD AND SYSTEM FOR GENERATING AN X-RAY IMAGE

The present invention relates to systems and methods for generating X-ray images for eg diagnostic use or for use as a basis for calculations of eg bone parameters of a person.

More specifically, the present invention relates to methods and systems for generating X-ray images wherein two irradiations are performed at different X-ray energies in order to be able to correct the image from background noise and information relating to eg soft tissue.

Systems of this type may be seen from eg US patent No. 5,204,888 issued to Tamegai et al. The Tamegai patent suggests two different systems, one of which uses four K-shell filters for obtaining two close-to-monochromatic beams at different mean energies. Thus, a total of four images are obtained and subsequently subtracted in pairs.

This method has the disadvantage that the subtraction of the information in one image by that of another means subtracting two large but similar numbers for determining the value of the individual pixels. The two resulting images are subsequently used as the basis for the final image wherefrom the Bone Mineral Content of bones is calculated. The uncertainty of this operation is obvious and will reduce the feasibility of this method for eg quantitative determination of information from the resulting image.

The other method suggested in the Tamegai patent is one wherein the two X-ray energies are generated simultaneously by using a single K-shell filter for splitting the single intensity top as emitted by an X-ray tube into two tops for use in the two images.

This method has two major disadvantages, namely the fact that the two irradiations are performed simultaneously and the fact that the mean energies of the two tops are positioned

relatively close to each other. Therefore, a complex setup is required in order to be able to separate the two images for further use.

The present method relates to a method where a single K-shell filter is used for filtering the X-ray energy spectrum emitted by an X-ray tube in order to obtain a beam of more monochromatic radiation.

It has been found that by selecting a suitable K-shell filter and X-ray radiation having a related mean energy, the energy distribution of the X-ray radiation transmitted by the K-shell filter may have a pronounced peak in the X-ray spectrum with only little spectral energy above the K-shell energy, thus producing a largely monochromatic X-ray spectrum as desired.

By requiring that the maximum intensity of X-ray radiation transmitted by the K-shell filter and having an energy higher than the K-shell energy is 20% of the total X-ray radiation transmitted by the K-shell filter, the resulting radiation is suitable for use in eg BMD/BMC measurements.

Thus, using the above-mentioned technique, suitable images may be obtained at suitable and selected X-ray energies using only two K-shell filters and without being forced to perform mathematical operations which introduce large uncertainties in the final result.

Therefore, it is an object of the invention to provide a system which may be used for the determination of BMD/BMC of bones using X-ray attenuation. In addition, the present system is preferably cheap in manufacture in order to provide a system which may be procured by e.g. specialized physicians in order to provide screening of women after the menopause in order to prevent accidental bone fractures caused by unnoticed excessive bone loss.

Furthermore, the present system may be manufactured to be extremely rugged and stable, whereby a mobile system for use in e.g. local crises may be provided. In fact, the present system is one of the few which will be operational after having been dropped in parachute from an aeroplane or a helicopter. Thus, an X-ray imaging system may now quickly be available in eg trackless areas.

Thus, in a first aspect, the present invention relates to a system for generating an X-ray image of an object, the system comprising:

- a source of X-ray radiation for generating a beam of X-ray radiation,
- a first K-shell filter having a first K-shell energy,
- means for directing a first beam of X-ray radiation having a first mean energy through the first K-shell filter and through the object along a first path, the first mean energy being in the interval of 70-130% of the first K-shell energy so that the intensity of the X-ray radiation transmitted by the first K-shell filter having an energy above the first K-shell energy is less than 20% of the total X-ray radiation transmitted by the first K-shell filter,
- means for detecting the X-ray radiation transmitted by the first K-shell filter and by the object,
- means for generating a first set of image data from the detected X-ray radiation transmitted by the first K-shell filter and by the object,
- a second K-shell filter having a second K-shell energy,
- means for directing a second beam of X-ray radiation having a second mean energy through the first K-shell filter and through the object along a second path similar to the first path, the second mean energy being in the interval of 70-130% of the second K-shell energy so that the intensity of the X-ray radiation transmitted by the second K-shell filter having an energy above the second K-shell energy is less than 20% of the total X-ray radiation transmitted by the second K-shell filter,

- means for detecting the X-ray radiation transmitted by the second K-shell filter and by the object,
- means for generating a second set of image data from the detected X-ray radiation transmitted by the second K-shell filter and by the object, and
- means for generating an image from the first and second sets of image data.

In the present context, a source of X-ray radiation may be all known sources of X-ray radiation. However, preferably the source is able to emit radiation having a substantially stable but variable mean energy and intensity.

A K-shell filter is a type of filter wherein X-ray radiation is filtered by the absorption of K-shell electrons of the material. This type of filter is commonly used in X-ray applications, such as in the above-mentioned Tamegai patent.

At present, the first K-shell filter preferably comprises a material chosen from the group consisting of: Cs, Ba, La, Ce, Pr, Nd, Sm, Eu, Gd, Tb, Dy, Ho, Er, Tm, Yb, Lu and Hf, combinations, salts or oxides thereof.

In addition, the second K-shell filter preferably comprises a material chosen from the group consisting of: Ho, Er, Tm, Yb, Lu, Hf, Ta, W, Re, Os, Ir, Pt, Au, Hg, Tl, Pb, Bi, Th and U, combinations, salts or oxides thereof.

The material or composition will depend on the parameters of the X-ray radiation desired for the first and/or second set of image data.

Often, if a certain K-shell material is preferably avoided for a reason, a corresponding other material may be selected and the mean energy of X-ray radiation emitted from the X-ray source may be adapted thereto so that the X-ray radiation transmitted by the selected corresponding material may obtain parameters close to those desired.

Usually, especially if the system is used for generating images for use in BMD/BMC determinations using anterior lumbar spine measurements, the first K-shell energy is in the interval of 35-55 keV and the second K-shell energy is preferably in the interval of 65-120 keV.

A suitable first K-shell filter comprises Ce and a suitable second K-shell filter comprises Au.

Depending on the thickness of the object (typically a patient), another suitable first K-shell filter comprises Gd. However, the second K-shell filter may still comprise Au.

Alternatively, K-shell energies of 20-36 keV may be desired if X-rays are desired of an arm or for use in mammography.

Due to the fact that only 20% of the total intensity transmitted by the first K-shell filter may be due to radiation having an energy exceeding the first K-shell energy, the first mean energy is preferably in the interval of 80-120%, such as in the interval of 90-110%, and more preferably in the interval of 95-105%, or in the interval 100-110%, of the first K-shell energy.

The same applies to the second image, whereby the second mean energy is preferably in the interval of 80-120%, such as in the interval of 90-110%, and more preferably in the interval of 95-105%, or in the interval 100-110%, of the second K-shell energy.

Preferably, the system comprises means for holding the first and the second filters in an operating position one at the time. These means for holding the first and the second K-shell filters in the operating position are preferably interconnected and are constituted by a filter holding means having a moving means adapted to move either filter into the operating position.

In this manner, a simple system may be provided for interchanging the filters without having to interchange other physical elements of the system. This is one of the features which makes the present system a very stable system.

In order to obtain a beam of X-ray radiation more monochromatic than the first beam as emitted by the X-ray source, the first beam of X-ray radiation has a first spectral width and the X-ray radiation transmitted by the first K-shell filter preferably has a more narrow spectral width.

At present, the spectral width of the X-ray radiation transmitted by the first K-shell filter suitably has a spectral width expressed as Full Width at Half Maximum (FWHM) being in the interval of 0.05-0.3, such as in the interval of 0.05-0.2.

The same applies to the second beam, whereby the second beam of X-ray radiation has a second spectral width expressed as Full Width at Half Maximum (FWHM) and wherein the X-ray radiation transmitted by the second K-shell filter preferably has a more narrow spectral width, such as in the interval of 0.05-0.3, preferably in the interval of 0.05-0.2.

In order to have a suitable efficiency in the detection of the X-ray radiation, it is presently preferred that the means for detecting the X-ray radiation transmitted by the first K-shell filter and the object comprise a first scintillator means for converting at least part of the X-ray radiation to lower energy radiation. The advantage of this conversion of radiation is that the X-ray radiation may be converted to radiation which may more easily be detected.

According to the present invention, the radiation is preferably detected in a manner so that images of the object may be provided. One radiation detector which may generate image data is a CCD. Thus, the means for detecting the X-ray radiation transmitted by the first K-shell filter and the object

preferably comprise a first CCD for detecting the lower energy radiation.

Naturally, the same applies to the second irradiation of the object, whereby the means for detecting the X-ray radiation transmitted by the second K-shell filter and the object preferably comprise a second scintillator means for converting at least part of the X-ray radiation to lower energy radiation, and that, in addition, the means for detecting the X-ray radiation transmitted by the second K-shell filter and the object preferably comprise a second CCD for detecting the lower energy radiation.

Another feature rendering the present system a stable system is the fact that vacuum image amplifiers are preferably not employed. Compared to CCD's, these amplifiers are much more sensitive to eg shock and vibrations and are very costly.

In order to save production costs a.s.o. the means for detecting the X-ray radiation transmitted by the first K-shell filter and the object preferably constitute the means for detecting the X-ray radiation transmitted by the second K-shell filter and the object. A suitable scintillator means comprises Gd_2O_2S as an active substance having a density thereof of 50-450 mg/cm^2, such as 100-200 mg/cm^2.

As the generation of the final image usually does not take place before both sets of image data have been obtained, the means for generating the first set of image data suitably comprise means for transferring data from the means for detecting the X-ray radiation transmitted by the first K-shell filter and the object and means for storing this data in a first data storage as the first set of image data.

Also, the means for generating the second set of image data preferably comprise means for transferring data from the means for detecting the X-ray radiation transmitted by the second K-shell filter and the object and means for storing

this data in a second data storage as the second set of image data.

It is often desired to be able to monitor and optionally or additionally to limit the radiation dose received by the object/patient to remain under a given threshold. Thus, the system preferably further comprises an X-ray radiation measuring means positioned so as to determine the intensity of the X-ray radiation emitted by the first or the second K-shell filter before being transmitted through the object. A suitable X-ray radiation measuring means is an ionization chamber.

In this manner, the system will be able to monitor the surface dose received by the object.

It is therefore a further object of the invention to provide an X-ray imaging system in which the surface dose received by the object/patient may be monitored and additionally optionally limited to eg a limit set by health authorities.

In order to be able to terminate the radiation when a maximum surface dose has been received by the object, the system preferably further comprises means for comparing the intensity determined by the X-ray radiation measuring means to a predetermined threshold value and means for terminating irradiation of the object once the measured intensity exceeds the threshold value.

Naturally, the predetermined threshold value may be selected, avoided and altered depending on the circumstances, such as on the type of object.

As will be described in connection with the drawing, the absorption of X-ray radiation in an object depends not only on the energy thereof but also on the thickness of the layer of the object that has to be penetrated. The lower the X-ray

energy, the larger the absorption in the object, and the larger the thickness to penetrate, the larger the absorption.

Therefore, if the lower X-ray energy radiation (the first beam as filtered by the first K-shell filter) has an energy too low, an unsuitably low intensity may be transmitted by a thick object.

On the other hand, a lower X-ray energy radiation having an energy too high in relation to a quite thin object may transmit an unsuitably large intensity.

Therefore, in an especially important aspect, the present invention relates to a system as described above comprising at least three K-shell filters between which the first and the second K-shell filter are selected.

Thus, a number of K-shell filters are provided in the system and the suitable ones may be selected depending on eg the object.

As the above-mentioned problem is especially seen at the lower energy X-ray radiation (the first beam), one of the at least three K-shell filters preferably constitutes the second K-shell filter and the first K-shell filter is suitably selected from the remaining K-shell filters, and the system preferably further comprises means for selecting the first K-shell filter from the remaining K-shell filters.

Usually, the same higher energy X-ray energy (of the second beam) may be used for all realistic thicknesses of a given type of objects.

Therefore, it is an object of the invention to provide an X-ray imaging system in which the lower X-ray energy may be chosen from a multitude of candidates in order to provide the optimum image.

To the knowledge of the applicant, a system of this type has not been seen prior to the filing date of the present application.

An especially suited embodiment is one adapted to generate images of bone structures in humans comprising three K-shell filters wherein one constitutes the second K-shell filter and comprises Au and wherein the first K-shell filter is selected between one K-shell filter comprising Gd and one comprising Ce. In this embodiment, the Ce filter is used for thin and normal persons and the Gd filter for thicker persons.

Naturally, the images generated by the present system may be used for eg diagnostic purposes, as the background correction wherein eg the soft tissue of eg X-rays of persons provide quite detailed images of the dense part (bones or eg cancer tissue or other tumors) of the person.

Alternatively, since dense and light (soft tissue) structures can be separated, the dense part of the image may be removed leaving the possible underlying light structures to be seen in the image.

Another use of the image generated is for eg predicting parameters of the structures in the image, eg the BMC or BMD of bones.

Thus, in one embodiment, the system further comprises means for, on the basis of the image, determining parts of the image relating to bone structures of the object and means for, on the basis of the image, determining information on the determined bone structures.

Preferably, the means for determining information on the bone structures comprise means for estimating the Bone Mineral Density or the Bone Mineral Content of the bone structures.

The estimated Bone Mineral Density or Bone Mineral Content may be estimated individually for a number of bones in the bone structure in the image.

Additionally or optionally, the estimated Bone Mineral Density or Bone Mineral Content may be estimated as a mean value for a number of bones in the bone structure in the image.

Obviously, the present system may be used for a large variety of objects and for eg determining a large variety of parameters of the objects. However, a preferred embodiment of the system in one wherein the bone structure of the object is part of the spine of a human and wherein the Vertebral Area, the Vertebral Height, the Vertebral Diameter, the Bone Mineral Density, the Mineral Content per Length, the Bone Mineral Content is determined both for individual vertebral bodies of the image and as mean values thereof.

In another embodiment, the bone structures of the object may be removed from the image in order to provide a better image of the soft tissue. The main requirement for removing part of the information of the image so as to enhance other parts thereof is that a suitable difference exists in absorption between the background elements and the interesting elements.

If the first and second sets of image data are constituted by a first and a second image, the information of which relates to the objects absorption of the first and second beams of X-ray radiation transmitted through the first and second K-shell filters, respectively, this setup will provide that calculating means may be provided for generating an image which pixel by pixel is calculated from corresponding pixels of the first and second images and predetermined values.

In this manner, the background correction of the image may take into account variations in local areas, as the correction for the individual pixel may be determined.

Naturally, in order to be able to use the two sets of image data for eg background correction, the first and second paths along which the X-ray radiation for the first and second image data travels are preferably substantially the same. Otherwise, a pixel-for-pixel background correction may not be possible. In the ideal case, the two images should be of the object taken from exactly the same path.

Especially, if the image generated is to be used for eg quantitatively determining parameters from eg bones in the image, it is highly desired that the scaling of the elements in the image is known.

In the example where BMD or BMC is to be determined from an image containing bone information, two identical bones may have different sizes in the image, if translated in the direction of the X-ray radiation penetrating the bone.

In this situation, the BMD per length and other parameters of the bone may not be correctly calculated.

Another problem is that part of the processes of the vertebral bodies are overlapping with the central body in this image. This will erroneously increase the apparent density of bone in the central body.

Therefore, the system preferably further comprises means for directing a third beam of X-ray radiation through the object in a third direction different from the first and the second directions, means for detecting X-ray radiation transmitted by the object and means for generating a third set of image data from the detected X-ray radiation transmitted by the object.

From this third set of image data, any deviation of the object, in the direction of the first and second beams, from a standard position may be detected and compensated for. An

example of a procedure performing this task is described in connection with the drawing.

This third set of image data will also provide additional information of processes overlapping with the central body in the two first sets of image data, whereby the two first sets of image data or the final image may be corrected for this error.

In a second aspect, the present invention relates to a method of obtaining an X-ray image of an object, the method comprising:

- providing a first K-shell filter having a first K-shell energy,
- producing a first beam of X-ray radiation having a first mean energy being in the interval 70-130% of the first K-shell energy,
- directing the first beam through the first K-shell filter, so that the intensity of the X-ray radiation transmitted by the first K-shell filter having an energy above the first K-shell energy is less than 20% of the total X-ray radiation transmitted by the first K-shell filter, and further through the object along a first path,
- detecting X-ray radiation transmitted through the first K-shell filter and the object,
- from the detected X-ray radiation transmitted through the first K-shell filter and the object, generating a first set of image data,
- providing a second K-shell filter having a second K-shell energy,
- producing a second beam of X-ray radiation having a second mean energy being in the interval of 70-130% of the second K-shell energy,
- directing the second beam through the second K-shell filter, so that the intensity of the X-ray radiation transmitted by the second K-shell filter having an energy above the second K-shell energy is less than 20% of the total X-ray radiation transmitted by the second K-shell filter, and

further through the object along a second path similar to the first path,

- detecting X-ray radiation transmitted through the second K-shell filter and the object,
- from the detected X-ray radiation transmitted through the second K-shell filter and the object, generating a second set of image data,
- from the first and second sets of image data, generating an image of the object.

Again, by properly selecting the mean energy of the X-ray radiation to be filtered and the K-shell energy of the filter, radiation well suited for eg BMD/BMC measurements of bones may be provided.

As described above, the first mean energy is preferably in the interval of 80-120%, such as in the interval of 90-110%, preferably in the interval of 95-105%, or in the interval of 100-110%, of the first K-shell energy.

Also, the second mean energy is preferably in the interval of 80-120%, such as in the interval of 90-110%, preferably in the interval of 95-105%, or in the interval of 100-110%, of the second K-shell energy.

An especially preferred embodiment of the present method is one wherein at least three K-shell filters are provided and which additionally comprises the step of selecting from the at least three K-shell filters a K-shell filter to constitute the first K-shell filter and a K-shell filter to constitute the second K-shell filter.

Depending on eg the type of object, the said selection may be based on the weight of the object, the thickness thereof in the direction of the first and second beams or the length of circumference of the object.

The at least three K-shell filters are preferably held by a filter holding means and, subsequent to said selection, a moving means may be operated in accordance to the selection in order to move the selected K-shell filter to constitute the first or the second K-shell filter into a position where it may filter the first or second beams, respectively.

In this manner, positioning and change of filters may be facilitated.

In order to facilitate monitoring of the surface X-ray dose received by the object, the method may further comprise the steps of determining the intensity of the first and/or of the second beams transmitted by the first and second K-shell filters, respectively, using an X-ray radiation measuring means.

If an upper limit of this surface dose is set, the first beam may be terminated when the determined intensity thereof exceeds a first predetermined value. The same applies to the second beam which may be terminated when the determined intensity thereof exceeds a second predetermined value.

As described above, the step of detecting the X-ray radiation transmitted by the first K-shell filter and the object preferably comprises introducing a first scintillating means in the X-ray radiation transmitted by the first K-shell filter and the object, in order to transform the X-ray radiation to lower energy radiation, and detecting the lower energy radiation with a first CCD.

In addition, the step of detecting the X-ray radiation transmitted by the second K-shell filter and the object may comprise introducing a second scintillating means in the X-ray radiation transmitted by the second K-shell filter and the object, in order to transform the X-ray radiation to lower energy radiation, and detecting the lower energy radiation with a second CCD.

In order to facilitate the above-mentioned pixel-by-pixel correction, it is preferred that the step of generating the first set of image data comprises the step of generating a first image comprising information relating to the objects absorption of the X-ray radiation transmitted by the first K-shell filter.

In addition, the step of generating the second set of image data preferably comprises the step of generating a second image comprising information relating to the objects absorption of the X-ray radiation transmitted by the second K-shell filter.

In this manner, the step of generating the image may comprise the step of calculating, pixel by pixel, the image from corresponding pixels of the first and second images and predetermined values.

As described above, a preferred embodiment of the method is one comprising the steps of determining parts of the image relating to bone structure of the object and of calculating, based on the image, parameters of the bones in the image.

The calculated parameters may be chosen from the group of: Bone Mineral Density of individual bones in the image, a mean Bone Mineral Density of a group of bones in the image, Bone Mineral Content of individual bones in the image or a Bone Mineral Content for a group of bones in the image.

Naturally, also other related parameters may be determined from the image.

In order to be able to determine the scaling of the eg bones in the image, the method preferably further comprises the steps of:

- producing a third beam of X-ray radiation,
- directing the third beam through the object along a third path different from the first and the second paths,

- detecting X-ray radiation transmitted through the object,
- from the detected X-ray radiation transmitted through the object, generating a third set of image data, and wherein the step of generating the image comprises basing said generation on the first, second and third sets of image data.

As described above, in this manner, any translation of the object along the direction of the X-ray of the first and second beams may be detected and compensated for.

In addition, the contribution from processes erroneously adding to the apparent bone density of the central body may be evaluated from this third set of image data.

In the following, preferred embodiments of the instrument according to the invention for generating X-ray images of vertebrae will be described with reference to the drawing wherein:

Fig. 1 is a cross sectional illustration of a preferred embodiment of the instrument of the invention,

Fig. 2 illustrates an initially positioned grid pattern for use in the determination of BMD in bones,

Fig. 3 illustrates the grid pattern of Fig. 2 in a final position,

Fig. 4 illustrates the splitting of the quadrangles of the grid pattern of Fig. 2 into four segments each, and

Fig. 5 illustrates a typical histogram of a segment of a quadrangle of Fig. 4 from a normal person.

As described above, the instrument according to the invention may be used for generating usual X-ray images for use in e.g. diagnostics.

Due to its image processing capabilities, the present invention is especially suited for obtaining good images of bone tissue, since soft tissue structures can be removed by a computerized image processing technique executed on a dual set of images acquired with different X-ray spectral energies.

Also, using the present instrument for generating images of bones, a reduction in X-ray dose received by the patient 22 may be obtained compared to the known method, even though two X-ray irradiations are performed compared to the single irradiation performed in the art.

Mainly, this reduction in X-ray dose received by the patient is due to the efficiency and dynamic range of the presently preferred CCD for transforming the radiation to image data, compared to X-ray films and conventional image intensifiers.

Another reason is the computational analysis of the two images acquired which allows removal of soft tissue structures and thereby enhancement of imaging of bone structures.

The presently preferred instrument for generating X-ray images is illustrated in Fig. 1. This instrument comprises an upper part 2 for positioning on one side of the patient and a lower part 4 for positioning opposite to the upper part 2 so that the part of the patient 22 of which the X-ray image is to be taken is positioned between the two parts 2 and 4.

The upper part 2 comprises an X-ray tube 6 (such as a COMET, Switzerland, type XO 125A with a grid) having a stationary or rotating anode, grid controlled anode current, oil cooling and a high voltage power of approx. 1kW. The high voltage is generated by a high-frequency converter 8 (such as a ARC16CH from SMAM, Muggio, Milano, Italy) and is specified to be in the interval 65kV/10mA to 100kV/4mA. Both the voltage and the current should be precisely controllable in order for the generated X-ray spectrum and the intensity of the X-ray

radiation to be controllable. If the anode is of the fixed type, only low current use is possible, and efficient cooling of the anode should be established. Preferably, the temperature of the oil is monitored and an overheating circuit breaker is used.

In addition, the upper part 2 comprises a K-shell filter arrangement comprising 2 filters 12 and 14 and a stopping means 16 for positioning in front of the tube 6 for filtering or stopping, respectively, any radiation emitted from the tube 6.

The stopping means 16 is comprised in the present embodiment in order to ensure that radiation is only emitted from the upper part 2 when this is intentional. At present, the stopping means 16 consists of a layer of lead. However, a number of other materials may also be used for this purpose. Mainly, the thickness of the material should be suitable for stopping any radiation unintentionally emitted from the tube 6.

Alternatively, the stopping means 16 may be constituted by a material, such as Au, which may both act as a K-shell filter in the operation of the instrument and as a means for stopping at least the low energy part of X-ray radiation accidentally or unintentionally emitted from the tube 6. The low energy part of the radiation is that which experiences the largest absorption in the patient and therefore is most harmful to the patient.

Preferably, the filters 12 and 14 and the stopping means 16 are held by a holding means 18. The holding means 18 is preferably of a type which will automatically hold the stopping means 16 in front of the tube 6 at all times except when one of the filters 12 and 14 is desired for filtering radiation emitted from the tube 6. In this manner, unintentionally emitted radiation from the tube 6 may not add to the X-ray dose received by the patient.

This holding means 18 may be shaped as a circle and the individual filters and the stopping means may be arranged as sectors of a circle or simply as circular filters arranged in a circle. Rotating the holding means may then position the desired filter/stopping means in front of the tube 6. Optionally, the holding means 18 may comprise a hole where through X-ray radiation may pass unaltered for calibration purposes.

In the present embodiment, however, the filters 12 and 14 and the stopping means 16 are held in the holding means 18 in a manner so that they are adjacent to each other and with the stopping means 16 between the two filters 12 and 14.

This holding means 18 is spring biased to a position where the stopping means 16 is positioned in front of the tube 6. Thus, one of the filters 12 or 14 will only be positioned in front of the tube 6 when the moving means (not shown) are energized to move the holding means 18 to either side. This feature ensures immediate positioning of the stopping means 16 in front of the tube 6 as soon as the power to the moving means (not shown) of the holding means 18 is cut off - intentionally or unintentionally. The moving means moving the holding means 18 may eg be based on the use of a solenoid.

Naturally, the holding means 18 may be changed so as to hold any number of filters, and the stopping means 16 may, of course, be omitted, should this be preferred.

In order to reduce the size of the filters 12 and 14 and in order to reduce the angle of scattered X-ray radiation relative to the angle of radiation directly from the tube 6, the holding means 18 is preferably positioned as close to the tube 6 as possible.

In the upper part 2 is also comprised an ionizing chamber 20 for measuring the X-ray radiation transmitted by the filter 12 or 14 when positioned in front of the tube 6.

Introduction of this ionizing chamber 20 enables the operator to exactly monitor the X-ray surface dose received by the patient 22, as this feature directly measures the radiation emitted towards the patient 22. The present ionizing chamber 20 not only enables the operator to monitor the X-ray dose received by the patient 22, it also allows the operator to define a maximum acceptable dose. Upon receipt of this dose by the patient 22, the present instrument may be controlled so as to automatically terminate the irradiation of the patient 22 - irrespective of the quality of the resulting image (see further below).

A collimator or tubus 21 is typically introduced in the upper part 2 in order to absorb scattered radiation and radiation emitted in other directions than the target, i.e. the X-ray sensitive element of the lower part 4. In the present instrument, the tubus 21 should remove or attenuate radiation not directed towards the collimator 24.

The lower part 4 of the present instrument comprises a point-focusing collimator 24 having the anode spot of the tube 6 in the point of focus. This collimator 24 may either consist of a plate of lead with holes therein all pointing towards the focal point of the X-ray emitting anode or, as is preferred in the present system, of two identical line-focusing collimators - also called a grids - arranged on top of each other at an angle of 90° in such a way that the focal lines of the grids substantially intersect at the anode of the tube 6. At present, the preferred grids comprise a carbon fibre (as opposed to Al) cladding in order to reduce unintended absorption of X-ray energy in the grid plates.

The presently preferred grid comprises lead strips of a slightly wedge-shaped form so that they point towards a line through the anode of the tube 6 and being interspaced by paper of a suitable thickness.

This collimator 24 functions so that the X-ray radiation will be transmitted by a paper interspacer without any significant attenuation but through the strips with significant attenuation. Thus, only radiation having a direction defined by the direction and physical dimensions of the strips in combination from the two grids will be transmitted by the collimator 24.

The presently preferred collimator is a SMIT RÖNTGEN (The Netherlands) paper-interspaced collimator that preferably has a focal length f=100cm, a height/width ratio of 10 (of each cell), 44 strips/cm, a total dimension of 24 cm x 24 cm, thus having a Bucky-factor (B-factor) of 4.4.

The function of the collimator 24 is that of removing stray X-ray radiation being e.g. elastically scattered in the patient 22 or in the instrument and which would otherwise add to the background noise of the images generated.

In order to ensure optimal use of the X-ray radiation transmitted through the patient 22 and the collimator 24 it is preferred to transform it into radiation which a CCD 26 may detect more efficiently.

Thus, a scintillator 28 is introduced into the beam of X-ray radiation transmitted through the patient 22 and the collimator 24 for converting the X-ray radiation to radiation to which the CCD 26 is more sensitive.

At present, a Kodak Lanex Fast scintillator 28 is preferred having Gd_2O_2S as the active substance and wherein the concentration thereof is 150 mg/cm^2. However, also all other typical standard scintillators may be used. Calculations have shown that the above-mentioned Gd_2O_2S-containing scintillator gives a suitable conversion of the X-ray quanta in the present setup.

At present, the physical dimensions of the active area of the scintillator 28 have been chosen to be 22 cm x 22 cm.

Subsequently to the conversion in the scintillator 28 of the X-ray radiation to visible radiation, the visible radiation is transmitted to the CCD 26 for detection thereof.

Preferably, the visible radiation is directed to the CCD 26 by means of a mirror 30, preferably a plane surface mirror comprising a thin layer of Al evaporated on a plane glass plate. Below the mirror, a sandwich of metal sheets is formed to absorb X-ray radiation transmitted through the scintillator 28 and mirror 30 with minimum X-ray reflection. This sandwich preferably consists of a layer of Cu (thickness = 1mm) and a layer of Pb (thickness = 3mm).

The function of the mirror is to not have the CCD 26 positioned at a position in the instrument where any X-ray radiation not converted in the scintillator 28 may impinge on the CCD 26 and thereby add noise to the detected image. Another advantage of this solution is the fact that the physical height of the lower part 4 may be reduced due to this bending of the optical path therein.

The visible radiation emitted by the scintillator 28 diverges. The physical dimensions and the positions of the scintillator 28 and of the CCD 26 are typically so selected that optics 32 are desired between these elements in order to collect, direct and focus the visible radiation on to the CCD 26.

Adapting the optics 32 between the scintillator 28 and the CCD 26 so as to ensure that a suitable amount of the visible light is transferred to the CCD 26 and at the same time not excessively distorting the graphic information of the radiation will be normal knowledge to the skilled person.

At present, the specifications are that the aperture of the optics should be 80 mm, the opening ratio 0.7, the focal length 50 mm and that the last lens (not shown) (towards the CCD) should have a flat outer face.

Preferably, the CCD 26 is positioned as close as possible to the last lens.

At present, the following physical dimensions are preferred: diameter of the first lens (80mm) (closest to the mirror 30) of the optics 32, the scintillator 28 (active area: 22 cm x 22 cm) and the distance therebetween (556mm).

In order to reduce the background noise in the detections of the CCD 26, this element is preferably cooled by means of e.g. a Peltier element (not shown). In addition, in order to reduce the effect of any stray X-ray radiation in the system, the CCD 26 is preferably protected by a layer of lead.

As is typical in the art, a light detector (not shown) may be positioned adjacent to the CCD 26 or at another position in the lower part 4 in which it is able to detect radiation emitted by the scintillator 28. This light detector may be used to avoid more irradiation of the patient than that required in order to obtain a suitable image quality. This is done by automatically turning off the tube 6 when a pre-determined amount of radiation has been detected by the light detector. The predetermined amount of radiation is determined so as to give an overall irradiation of the CCD 26 suitable for generating an acceptable image quality.

The output of the CCD 26 is connected to a PC type computer (not shown) comprising hardware consisting of standard interface components in order for the computer to be able to control the operation of the present instrument and for receiving the image data from the CCD 26. Furthermore, the computer should be able to perform operations on the image

data received from the CCD 26 in order to at least produce the final image.

In addition, as will be described below, the computer may additionally comprise software enabling the computer to perform calculations of e.g. parameters relating to the BMD of bones represented in the final image. The preferred method of calculation is described below.

A number of the elements of the instrument, such as the scintillator 28, the collimator 24, the optics 32, the CCD 26 and the mirror 30, may be controlled by the computer which may alter their positions in the instrument during e.g. a calibration of the instrument. It may be desired that the scintillator 28 comprises a frame having light emitting diodes in e.g. each corner for use in the calibration of the image positioning on the CCD 26. These light emitting diodes may also be used in the calibration of the pixel size in spatial units in that the distance between the LED's is known and in that the number of pixels between the images thereof may be determined.

The light detector may be calibrated by performing a number of irradiations (without patient 22) at different intensities and correlate the illumination measured by the CCD 26 with the read out of the light detector. The ionization chamber 20 may be calibrated in the same manner.

In order to correlate the acceleration voltage of the tube 6 to the K-shell energy of the filters 12 and 14 so as to obtain a beam of X-ray radiation having a suitable spectrum, a calibration method may be performed during which the acceleration voltage of the tube 6 is varied (and the anode current kept constant) from lower to higher voltages until radiation measured with and without the filter 12 or 14 has a pre-determined relation. This pre-determined relation may eg be determined on an instrument calibrated using an X-ray energy spectrometer.

Use of the instrument according to the invention for generating two patient X-ray images.

In order for images to be useful for e.g. diagnostic use, the resolution of the image should be sufficient for the physician to be able to extract the relevant information therefrom.

The resolution of the images generated by the present instrument is defined by the number of pixels in the CCD 26.

Typical high performance CCD's may be purchased having 1024x1024 pixels or 2048x2048 pixels.

At present, 2048x2048 pixels are contemplated being sufficient for most diagnostic purposes. It will, however, be possible to interchange such a CCD with one having another number of pixels, should this be desired or required. Naturally, the optics 32 should be adapted to the size of this new CCD.

One of the features of the present instrument is the fact that the instrument records two images of the same object acquired with different X-ray spectral energy distributions and uses these two images to generate the final image. In this manner, discrimination between bone and soft tissue may be performed so as to enhance the bone features.

The generation of an image will now be described.

In order for the CCD 26 to be sufficiently cooled, the Peltier element (not shown) should have been operating a few minutes (to have the CCD 26 cooled to -40°C or lower) before any readout from the CCD 26 should be considered.

In principles, two methods exist for reading out a CCD:

- a fast method only measuring the reset level at the beginning of each row of pixels and then measuring the level pixel by pixel in fast sequence through the remainder of the row, and

- a slow method integrating the voltage a suitable period of time (such as 2-10 microseconds) for each pixel for both the reset and the measuring level, and then digitizing the difference between the two levels with an accuracy of e.g. 12 or 16 bits.

Using the slow method, depending on the integration period and method, the reading out takes 2-13 μs or more per pixel, as it is possible to perform the analogue-digital conversion of the data simultaneous to the integration of the next pixel value.

The fast reading-out method presents an acceptable differential, but a poor absolute measuring accuracy. By the fast method, a 1024x1024 pixel CCD can be read out in a fraction of a second, which is required for eg a video display, and this method may be suitable for e.g. images that are to be observed or evaluated by the naked eye provided that a sufficient X-ray irradiation of the patient can be allowed.

If the image data are to form the basis of e.g. calculations, and if a digital representation with a high accuracy is required if a low patient dose is important, the slow method will be desired for its higher precision in determining the actual value for each pixel. To improve the read-out speed, some CCD's are equipped with 2 or 4 read-out amplifiers associated with ½ or a fourth of the total number of pixels. By similarly duplicating or quadrupling the read-out electronics, two or four times read-out speed may be obtained.

A CCD (such as a SITe, Oregon, USA, type SA0003 (former type TK1024)) having 1024x1024 pixels may therefore be read out in about 5 seconds (512.000 pixels in each channel, 10 μs each)

using the slow read-out method. The size of the pixels measured on the 220 mm times 220 mm large scintillator 28 is close to 0.22mm x 0.22mm which gives a suitable resolution for an X-ray image for visual diagnosis. This pixel range may be reduced to 0.12mm x 0.12mm by using a 2048x2048 pixel CCD thereby enhancing the resolution of the image on the expense of either read-out time or image quality.

Initially, the CCD 26 is read out using the same read-out method as desired in the subsequent image acquisition(s) in order to empty the CCD 26 of thermal electrons.

The thermal electrons added to the pixels during this reading out will then correspond to those detected during a typical read-out of subsequent images used for eg diagnostic purposes. Having read out the image, the CCD 26 will contain a distribution of thermal electrons corresponding to the actual pattern of reading out the CCD 26 and the time used therefore. Any immediately following image is therefor inherently and automatically compensated for the wedge shaped distribution of thermal electrons added during read-out giving a constant contribution (average) to all pixels. This technique is known to persons skilled in the art of highly sensitive CCD's, such as astronomers.

While emptying the CCD 26 for thermal electrons, the first, lower acceleration voltage is applied to the tube 6 while the grid voltage is negative (typically on the order of 2kV) so that no current is possible, and the desired filter 12 or 14 corresponding to the acceleration voltage of the tube 6 is positioned in front of the tube 6.

The grid voltage required for cutting off the electron beam depends on the actual X-ray tube used.

The interesting part of the patient 22, comprising the bone to be analyzed, has in advantage been positioned at an irradiation position between the holding means 18 and the

scintillator 28. In order to ensure that at least the interesting part of the patient 22 remains substantially immobilized during the irradiation and preferably during both irradiations and the intermediate waiting time, the patient 22 may be positioned on e.g. a couch (not illustrated).

When the first filter 12 or 14 is positioned in front of the tube 6, the patient 22 should remain immobilized until the two irradiations have been performed and exposure should preferably begin immediately after the first emptying of the CCD 26 is completed, as described above.

The irradiation of the patient 22 commences until either the ionization chamber 20 reports that the maximum surface dose has been received by the patient 22, the light detector reports a sufficient illumination of the CCD 26 or a predetermined irradiation time has been reached. Any of these parameters may be set or omitted.

Preferably, the exposure is terminated by the light detector when reaching a predetermined value giving an acceptable image and, hence, with minimum surface dose to the patient.

At this point, the grid voltage is again set negative and the stopping means 18 are closed so as to avoid further irradiation of the patient 22.

Subsequent to irradiation by the X-ray radiation having the first energy, the CCD 26 is read out using the same method as above. Meanwhile, the acceleration voltage is set to the next value and, the other filter 12 or 14 corresponding to the second X-ray energy is positioned in front of the tube 6.

Immediately after read-out, the patient 22 is irradiated with the X-ray radiation having the other energy, preferably the irradiation for the second image is terminated by the light detector reaching a value giving an acceptable limit, thus giving a minimum dose to the patient. Typically, the irradi-

ation time for the second irradiation is smaller than that for the first irradiation. It should be ensured that the patient 22 does not receive an excessive radiation dose and that the CCD 26 is not over-illuminated.

At the end of the second irradiation, the grid is set to negative voltage, and the stopping means 16 is again positioned in front of the tube 6. Subsequently, the patient 22 may move freely.

Then the second image is read out from the CCD 26 and into the computer.

In the acquired images, all pixel values contain a contribution corresponding to the number of thermal electrons acquired during a period of time corresponding to the actual exposure time plus the read-out time of the method used.

In order to compensate for this contribution, two "dark images" - one for each irradiation energy - are subsequently obtained by waiting for a period of time corresponding to the actual exposure time used and subsequently reading the thermal electrons added to the pixels using the same method as hitherto. These "dark images" are spatially low-pass filtered and subtracted from the respective images of the patient.

Alternatively, two dark images of a short, say 1 sec, and a long, say 10 secs, may be acquired and filtered in advance, for instance, when no patient is present, the proper background correction is then obtained by interpolating between these images corresponding to the actual exposure- and read out time.

It is highly preferably that the CCD 26 has the same temperature during irradiation and acquisition of the corresponding dark image.

The images thus obtained contain information relating to the illumination of the CCD 26. This information should be converted to information relating to the absorption in the patient. This conversion is performed by dividing the patient images with a prepared correction image obtained by illuminating the scintillator 28 for a relatively long period of time (such as on the order of 10s) in order to obtain a suitable reference image subsequently corrected in the same manner as the patient images. Before dividing the values of this reference image and the patient images, the values of the reference image are scaled to correspond to the incident X-ray illumination on the patient as measured by eg the ionization chamber 20 or the exposure time.

Preferably, separate reference images are acquired for each incident X-ray spectral energy used.

After this, the two corrected patient images will contain absorption values and form the basis for the generation of the final image calculated by the computer.

In this process, any geometric distortion of the images detected by the CCD 6 generated by the mirror 30 or the optics may be compensated for. Movements of the patient 22 between the two images may also be compensated for before the generation of the final image. Operations of this type, such as operations involving pattern recognition and two-dimensional correlation analysis, will be known to the skilled person.

If the energies of the X-ray beams used are properly chosen, the higher-X-ray-energy image will substantially correspond to the electron-density of the tissue whereas the lower-X-ray-energy image will contain information substantially on the mass density i.e. mainly bone, but alternatively also other dense tissue, such as cancer tissue.

A final combined image may therefore be produced by combining the information of the high and low energy X-ray images to produce an image of the bone structures where the soft tissue structures have been removed.

The thus obtained image may be used for either visual diagnostic purposes or form the basis of further image analysis in order to obtain quantitative information on BMD and BMC by using calibration values as described below.

The low-energy X-ray image is particularly sensitive to the thickness of the patient.

Therefore, preferably the present instrument for use in determining bone mass diagnostic images or BMD- or BMC-values of a patients bones incorporates more than one filter for defining more than one lower energy of X-ray radiation to be able to adapt the instrument to the thickness of the patient.

As described above, the higher X-ray energy is less critical, whereby the same higher energy may be used for all patients. This is not the situation for the lower energies.

The actual lower energy filter may be selected on the basis of a number of parameters, such as the waist measure of the patient, the weight of the patient or the thickness of the patient.

Another method may be that the patient 22 is positioned on a couch (not illustrated) as described above and is firstly subjected to an initial irradiation which serves the purpose of determining which lower energy should be used. As this determination is suitably based on the intensity of radiation transmitted through the patient 22, one of the lower X-ray energies should be used for this irradiation.

At present, a lower X-ray energy defining filter incorporating Ce as the K-shell filter (giving X-ray radiation having a

mean energy of on the order of 38 keV with a typical acceleration voltage of 65kV) is preferred for performing lateral lumbar scans of thin patients or patients having a normal thickness and Gd is preferred for thicker patients (giving X-ray radiation having a mean energy of on the order of 47 keV with a typical acceleration voltage of 75 kV). As the high energy filter, Au (giving X-ray radiation having a mean energy of on the order of 75 keV using a typical acceleration voltage of 105 kV) is a suitable choice for all patient thicknesses.

Depending on the properties of the material having the desired K-shell energy, the material may be employed as a thin foil or the like; materials of this type will typically be metals.

If the material has a tendency to oxidize, it may be preferred to either encapsulate it in order to prevent oxidization or it may be preferred to use the oxide of the material - such as in a ceramic material.

As the filtering properties are defined by the K-shell of the atom, these properties will not be changed to any significant degree by using eg the oxide of the material.

Ceramic materials suitable for K-shell filters in instruments of this type are manufactured by e.g. Forskningscenter Risø, Denmark, and metallic foils suitable are e.g. manufactured by KAMIS inc. NY, USA.

At present, the preferred Ce filter is a 0.7 mm thick Ce-ceramic comprising 0.4 g/cm^2 CeO_2 manufactured by Risø, Denmark. Alternatively, a suitable Ce foil may e.g. be 0.6 mm thick. The preferred acceleration voltage suitable for use with this filter is 60-70 kV.

The preferred Gd filter is made of a ceramic comprising 0.5 g/cm^2 of Gd_2O_3 or Gd_2O_2S. The preferred acceleration voltage suitable for use with this filter is 70-80 kV.

The presently preferred Au filter is a 0.8 g/cm^2 foil. The presently preferred acceleration voltage for use with this filter is 100-110 kV.

Calculation of the final image from two patient images

In the following, the preferred method of calculating the final image is described.

The present calculations are based on image data obtained using two X-ray energies from materials (patients) wherein three materials absorb: bone mineral, water and fat.

In the present context,

A_l denotes the attenuation of low energy radiation
A_h denotes the attenuation of high energy radiation
m_b denotes the density of bone mineral (g/cm^2)
m_v denotes the density of water equivalent tissue (g/cm^2)
m_f denotes the density of fat equivalent tissue (g/cm^2)

μ_{xx} denotes the attenuation coefficient (cm^2/g) with first index b, v or f for the material and with second index l or h for radiation energy.

Thus,

$$\ln A_l = m_b \cdot \mu_{bl} + m_v \cdot \mu_{vl} + m_f \cdot \mu_{fl}$$
$$\ln A_h = m_b \cdot \mu_{bh} + m_v \cdot \mu_{vh} + m_f \cdot \mu_{fh}$$

A fat index F may be defined:

$$F = \frac{m_f}{m_v + m_f} \Rightarrow m_f = m_v \cdot \frac{F}{1-F}$$

whereby

$$\ln A_l = m_b \cdot \mu_{bl} + m_v \cdot (\mu_{vl} + \frac{F}{1-F} \cdot \mu_{fl})$$
$$\ln A_h = m_b \cdot \mu_{bh} + m_v \cdot (\mu_{vh} + \frac{F}{1-F} \cdot \mu_{fh})$$

The ratio G between the absorption in soft tissue at low and high energy is:

$$G = \frac{(1-F) \cdot \mu_{vl} + F \cdot \mu_{fl}}{(1-F) \cdot \mu_{vh} + F \cdot \mu_{fh}}$$

whereby

$$m_b = \frac{\ln A_l - G \cdot \ln A_h}{\mu_{bl} - G \cdot \mu_{bh}}$$

The ratio of absorption G is as a function of the fat index F:

F	0.15	0.20	0.25	0.30	0.35	0.40
G	1.493	1.479	1.465	1.450	1.436	1.422

...... thin ...... medium ...... thick ......

In areas with no bone tissue:

$$\ln A_l = m_v \cdot \mu_{vl} + m_f \cdot \mu_{fl} = m_f \cdot (\frac{1-F}{F} \cdot \mu_{vl} + \mu_{fl})$$
$$\ln A_h = m_v \cdot \mu_{vh} + m_f \cdot \mu_{fh} = m_f \cdot (\frac{1-F}{F} \cdot \mu_{vh} + \mu_{fh})$$

whereby

$$F = \frac{\ln A_l \cdot \mu_{vh} - \ln A_h \cdot \mu_{vl}}{\ln A_l \cdot (\mu_{vh} - \mu_{fh}) - \ln A_h \cdot (\mu_{vl} - \mu_{fl})}$$

The absorption coefficients at 38 keV and 75 keV for hydroxy apatite, water and fat are:

cm^2/g	photo effect +	Compton effect	= Total
μ_{bl}	0.796	0.229	1.025
μ_{bh}	0.098	0.164	0.262
μ_{vl}	0.064	0.217	0.281
μ_{vh}	0.007	0.176	0.183
μ_{fl}	0.019	0.213	0.232
μ_{fh}	0.003	0.182	0.185

Similar values may be calculated by the skilled person by interpolation using published tables (such as NSRDS-NBS29).

A first approximation to the final image, consisting of m_b-values calculated pixel by pixel, can be calculated using a mean fat index of eg 0.25. It is contemplated that this image is adequate for most diagnostic purposes.

An improved image may be obtained by identifying areas of soft tissue in the approximated image and therefrom determining fat indexes specific for different image regions. This method is described below in connection with the calculation of BMD- and BMC values.

Due to the quantitative nature of the procedure, images to be used for BMD determinations should have a large precision in the actual reading of the individual pixels. On the other hand, a lower resolution of the image may be tolerated.

Thus, if the present instrument is to be used for generating images for BMD determinations, the CCD 26 may be operated in a manner slightly different from that described above.

Especially, the CCD 26 is preferably read out using the slow method in order to ensure a precise read-out of the number of quanta of visible light detected by each pixel.

On the other hand, a manner of both increasing the statistical certainty on the number of quanta detected by a pixel and of speeding up the read out procedure is a manner in which the pixels of the CCD 26 are binned in 2x2 pixel bins. In this manner, the pixels are binned to form 512x512 bins. Therefore, the CCD is read out faster and as four pixels are added, the statistical uncertainty on the detected number of quanta is lowered.

Other than this, the irradiation and reading out of the detected data will preferably be performed as described above.

In order to be able to determine the BMD of the bones irradiated, it may be preferred to also obtain at least one image of the patient from a direction other than the direction of the above images. This will be preferred in order to be able to determine the distance from a fixed point of the present instrument to the bones of the patient 22 in order to be able to calibrate the density measure of the bone.

In Fig. 1, in broken lines the instrument is illustrated tilted to as to be able to obtain images of the patient at different angles.

From this figure it is seen that the upper part 2 and the lower part 4 are preferably interconnected by a U-shaped means 54 in order to maintain the relative positions thereof during tilting of the instrument.

Thus, preferably an image is obtained from a direction perpendicular to the first direction. From this image, which may be obtained using the fast read-out of the CCD 26, the distance from e.g. the bone to eg the couch of the instrument may be determined. This distance should be introduced in the below calculations of the BMD of the bones as, otherwise, the density of the bone may be miscalculated due to this distance not being the distance contemplated in the calculations.

As a matter of fact, this additional image may not only be used for calibrating the dimensions of the bones of the two first images. The situation may also be reversed so that one of the first images is used for calibrating the dimensions of the last image so that the last image may also be used for BMD/BMC determination. Naturally, if this is the situation, two side-images should be taken using the low and the high X-ray energy and the slow read-out - as is the situation for the first two images.

Thus, the present instrument provides five different modes of operation:

1) BMD/BMC measurement based on images taken from the front or back of the patient (eg anterior lumbar spine),
2) the measurement of 1) with an image taken from the side to calibrate the dimensions so as to obtain more reliable values,
3) BMD/BMC measurement based on images taken from the side of the patient (eg lateral lumbar spine),
4) the measurement of 3) with an image taken from the front or back to calibrate the dimensions so as to obtain more reliable values, and
5) a combination of 2) and 4).

For determining BMD and BMC for the vertebral spine of a patient, optimum values will be obtained using mode 5) since certain parts of a vertebral body may be difficult to limit out in the images taken from the front or back. These parts (especially the processus spinosus and a large part of the processus tranversus'es) will have a BMD/BMC different from the actual body of the vertebral body, which is the organ of interest. In the side-image, it is possible to determine the contribution of these parts in the anterior image. On the other hand, naturally, there is more soft tissue background in the side images.

Therefore, from the side image, the contribution of these parts may be determined in one image and subtracted in the other. In fact, one image may be used for compensating the other, whereby more correct determinations of the bone parameters may be obtained.

In the following, mode 2) is illustrated for BMD and BMC analysis for the vertebral spine, since this analysis includes all principle elements of analysis including those required in methods 1), 3), 4) and 5) and those required for other bone structures after suitable adaptation of the Regions Of Interest.

In order to determine what in the image is soft tissue, what is lumbar bones and what is transverse processes (in the lumbar region called processus costarius), m_b is calculated for each pixel on the basis of a mean fat index of eg 0.25 which is usual for normal patients. This F-value gives G=1.465. It is contemplated that the resulting image will suffice for visual inspection by eg a physician - provided that the image has a suitable resolution.

As stated above, the resulting values are used for generating an image representing the estimated m_b values.

Over this image, a mask consisting of (for the vertebral spine) three (four may, however, be used) rectangles each having a line at the center thereof and a width of approximately thee mean vertebral widths - that is 3*44 mm= 132 mm. Preferably, this width is the same for all calculations. This operation is illustrated in Fig. 2.

Interactively, the operator may move or rotate these initially assembled rectangles so that the center point 64 of the middle rectangle 60 is positioned over L3, so that point 64 is positioned in the center of L3 and so that a line 74 running along the centers of the rectangles 58, 60 and 62 runs as well as possible through the center of L3.

Having positioned the point 64 in the center of L3, points 66, 68, 70 and 72 are defined as the points at the boundaries between the rectangles 58, 60 and 62 and being positioned on the center line 74.

Subsequently to the positioning of point 64, the points 66, 68, 70 and 72 are translated by the operator - in any order - and the rectangles are correspondingly "deformed" from their initial shape as the borders thereof follow the movements of the points 66, 68, 70 and 72. The points 66, 68, 70 and 72 are translated in a manner so that the resulting quadrangles totally comprise L2, L3 and L4. The result of this operation may be seen in Fig. 3.

At the end of this operation, the border lines between the quadrangles should be positioned between the vertebral bodies (that is, in the discuses).

Once the resulting mask (the three quadrangles) is positioned over L2-L4 and optionally also L5, each quadrangle is split up into four segments (See Fig. 4) and the histogram of the individual pixels is determined for each of the 12 (optionally 16) segments. A typical histogram of this type may be seen from Fig. 5.

For a typical person, the number of pixels in each histogram will be on the order of $132\ mm/2 * 35\ mm/2\ /\ 0.4^2\ mm^2 = 7200$.

The soft tissue will be represented by more than half thereof, the vertebral bodies for a little over 25% and the rest will represent processus costarius'es and discusses. The histogram for soft tissue will have a shape close to a Gauss distribution. The m_s of the distribution is best determined by using the areas around ±SD (60%), where the Gauss distribution has an inflexion. The area outside ±1.5 SD (30%) should not be introduced in the calculation of m_s, as thin areas with processus costarius'es and discs may otherwise contribute to m_s resulting in an underestimation of BMD. The

best estimation for the mean soft tissue level behind a vertebra is the mean value of m_s in the four segments around the vertebra.

The reason why the four histograms from the four segments relating to the same vertebra cannot be added before calculating m_s is the fact that the four Gauss curves often are translated to a degree so that pixels representing processus costarius'es in the histogram where the Gauss distribution is positioned the lowest will overlap pixels representing soft tissue in the histogram where the Gauss distribution is positioned the highest. Preferably, the four histograms relating to the same vertebra are represented simultaneously and even more preferably below each other on the screen of the computer.

The surface of a vertebra consists of a thin layer of cortical bone tissue while the inner parts of the vertebras is trabecullar tissue. The radiation penetrating the vertebras close to the surface will pass a longer distance of dense bone tissue, which is why pixels representing these edge areas may be found in the higher end of the histograms. These pixels may be used for defining the actual borders of the vertebras. The fraction of the higher pixel values that are required to be taken into consideration in order to obtain a well defined circumference of the vertebral bodies should be determined using eg interactive methods so that processus costarius'es and discs are not participating in the calculation of BMC and BMD.

In addition, osteoporotic patients often have a high content of bone mineral in processus costarius'es, while the content thereof in the vertebral corpus, which is the object of interest, is low.

One should keep in mind that the above calculated mean m_s is determined using a mean fat index of 0.25 and therefore an absorption ratio for soft tissue of 1.43. For the majority of

persons, the fat index varies from 0.15 (skinny persons) to 0.40 (extremely fat persons). However, as the dose received by the patient is measured by the ionization chamber, the absolute attenuation in the soft tissue may be determined for each of the two X-ray energies.

Therefore, the absolute fat index may be determined for the actual patient. As the fat index may vary from the lower to the upper lumbar vertebra - especially for pear-shaped patients - and furthermore from the left to the right side of the patient, a fat index (F) should be calculated for the soft tissue part of each of the 12 (optionally 16) segments and thereafter form the basis of a calculation of a mean F and a mean G for each lumbar vertebra. Preferably, the resulting F is shown on the screen of the computer.

Using the actual F and G values for the patient, new m_b values are calculated in all pixels. New histograms and new m_s values are calculated.

This procedure may, naturally, be adapted to any part of a patient comprising bone in order to provide an improved removal of soft tissue structures in the image.

For BMD and BMC calculations, the observed bone density must be related to the geometry of the bone. Hence, an edge detection is performed in order to determine the edges of the individual lumbar vertebras.

When a suitably large fraction of the higher pixel values are used so that the edges of the vertebras form a substantially interconnected circumference, this circumference is smoothed, eg using interpolation techniques in a polar coordinate system with the estimated column body center as origo, whereafter all pixels inside the circumference are taken as the interesting bone tissue. In this procedure, the processus traversus are excluded. At the top (between L1 and L2) and at

the bottom (between L4 and L5) of the Area Of Interest, the lines between the discs may form part of the circumference.

In the Area Of Interest the "total BMC", "BMC per unit of length = Total BMC divided by the height of the vertebra (the distance between point 1 and point 2, between point 2 and point 3 or between point 3 and point 4) is calculated for each vertebra. For each vertebra also a "mean BMC" and a "mean vertebral diameter" (the mean distance between the vertical sides of the vertebra) are calculated.

In these calculations, the magnification of the bone contour generated by the fact that the bone is positioned at a distance from the scintillator is taken into account. The distances from the center lines of the individual vertebral bodies to the scintillator surface is determined on the basis of a calibration and from the image taken at a different angle (see above) - preferably horizontally.

For each vertebra, the mineral densities are calculated from the pixel values in the defined Region Of Interest of the vertebra and the mean soft tissue level behind the actual vertebra. As an end result, the "Vertebral Area (VA cm^2)", "Vertebral Height (VH cm)", "Vertebral Diameter (VD cm)", "Bone Mineral Density (BMD g/cm^2)","Bone Mineral Content per Length (BMCL g/cm)", "Bone Mineral Content (BMC g)" is calculated both for the individual vertebral bodies and as mean values for all 3 (optionally 4) vertebral bodies.

An example of a list of results (which are mean values for normal Danish women: 53 years, height: 165 cm, weight: 63 kg and where the measurement was taken 1/2 year after the menopause; the typical patient for a preventive screening) may be:

Vertebrate	Area cm^2	Height cm	Diameter cm	BMD g/cm^2	BMCL g/cm	BMC g
L2	14.23	3.38	4.21	0.986	4.15	14.03

L3	15.29	3.50	4.37	0.969	4.23	14.82
L4	16.29	3.62	4.50	0.961	4.32	15.65
Total	45.81	10.50				44.50
Mean			4.36	0.972	4.24	

Together with this list, an image is preferably illustrated on the monitor of the computer wherein colors illustrate which pixels of the image formed part of the calculation of bone mineral and which pixels of the image formed part of the calculation of the background level.

The calibration of the ionization chamber charge with the area under the soft tissue peak in the histograms may be performed using eg an acrylic phantom in which marble discs are included having a known area and a known bone mineral equivalent BMD. This is standard quality control as performed in connection with BMD measuring equipment.

Using the above-described instrument and procedure, the total irradiation time per X-ray energy will be at the most 5 sec, so that the total period of time that a patient should remain immobilized will be on the order of 9 sec. This should be compared to the several minutes seen in the lumbar BMD measuring instruments presently available.

Although the BMD or BMC determination has been described in detail for the vertebrae of the patient, other bone structures are also subject to deterioration of bone mass, and hence are subject for BMD or BMD analysis. Following the same analysis principles as described above for the vertebrae, and adapting these procedures to the bone structures in question, specific analysis methods for these other bone structures can be designed or devised.

The skilled person will notice that the sequence of irradiation described above is of no importance and may if desired be rearranged.

CLAIMS

1. A system for generating an X-ray image of an object, the system comprising:

- a source of X-ray radiation for generating a beam of X-ray radiation,
- a first K-shell filter having a first K-shell energy,
- means for directing a first beam of X-ray radiation having a first mean energy through the first K-shell filter and through the object along a first path, the first mean energy being in the interval of 70-130% of the first K-shell energy so that the intensity of the X-ray radiation transmitted by the first K-shell filter having an energy above the first K-shell energy is less than 20% of the total X-ray radiation transmitted by the first K-shell filter,
- means for detecting the X-ray radiation transmitted by the first K-shell filter and by the object,
- means for generating a first set of image data from the detected X-ray radiation transmitted by the first K-shell filter and by the object,
- a second K-shell filter having a second K-shell energy,
- means for directing a second beam of X-ray radiation having a second mean energy through the first K-shell filter and through the object along a second path similar to the first path, the second mean energy being in the interval of 70-130% of the second K-shell energy so that the intensity of the X-ray radiation transmitted by the second K-shell filter having an energy above the second K-shell energy is less than 20% of the total X-ray radiation transmitted by the second K-shell filter,
- means for detecting the X-ray radiation transmitted by the second K-shell filter and by the object,
- means for generating a second set of image data from the detected X-ray radiation transmitted by the second K-shell filter and by the object, and
- means for generating an image from the first and second sets of image data.

2. A system according to claim 1, wherein the first beam of X-ray radiation has a first spectral width and wherein the X-ray radiation transmitted by the first K-shell filter has a more narrow spectral width.

3. A system according to claim 2, wherein the spectral width of the X-ray radiation transmitted by the first K-shell filter has a spectral width expressed as Full Width at Half Maximum (FWHM) being in the interval of 0.05-0.3.

4. A system according to claim 1, wherein the second beam of X-ray radiation has a second spectral width expressed as Full Width at Half Maximum (FWHM) and wherein the X-ray radiation transmitted by the second K-shell filter has a more narrow spectral width.

5. A system according to claim 4, wherein the spectral width expressed as Full Width at Half Maximum (FWHM) of the X-ray radiation transmitted by the second K-shell filter has a spectral width expressed as Full Width at Half Maximum (FWHM) being in the interval of 0.05-0.3.

6. A system according to claim 1, further comprising an X-ray radiation measuring means positioned so as to be able to determine the intensity of the X-ray radiation emitted by the first or the second K-shell filter before being transmitted through the object.

7. A system according to claim 6, further comprising means for comparing the intensity determined by the X-ray radiation measuring means to a predetermined threshold value and means for terminating irradiation of the object once the measured intensity exceeds the threshold value.

8. A system according to claim 1, comprising at least three K-shell filters between which the first and the second K-shell filter are selected.

9. A system according to claim 8, wherein one of the at least three K-shell filters constitutes the second K-shell filter and wherein the first K-shell filter is selected from the remaining K-shell filters, and further comprising means for selecting the first K-shell filter from the remaining K-shell filters.

10. A system according to claim 1, wherein the means for generating the image comprise means for removing low density structures from the image, thereby enhancing higher density structures therein.

11. A system according to claim 1, wherein the means for generating the image comprise means for removing high density structures from the image, thereby enhancing lower density structures therein.

12. A system according to claim 1, further comprising means for, on the basis of the image, determining parts of the image relating to bone structures of the object and means for, on the basis of the image, determining information on the determined bone structures.

13. A system according to claim 12, wherein the means for determining information on the bone structures comprise means for estimating the Bone Mineral Density or the Bone Mineral Content of the bone structures.

14. A system according to claim 1, further comprising means for directing a third beam of X-ray radiation through the object in a third direction different from the first and the second directions, means for detecting X-ray radiation transmitted by the object and means for generating a third set of image data from the detected X-ray radiation transmitted by the object.

15. A method of obtaining an X-ray image of an object, the method comprising:

- providing a first K-shell filter having a first K-shell energy,
- producing a first beam of X-ray radiation having a first mean energy being in the interval 70-130% of the first K-shell energy,
- directing the first beam through the first K-shell filter, so that the intensity of the X-ray radiation transmitted by the first K-shell filter having an energy above the first K-shell energy is less than 20% of the total X-ray radiation transmitted by the first K-shell filter, and further through the object along a first path,
- detecting X-ray radiation transmitted through the first K-shell filter and the object,
- from the detected X-ray radiation transmitted through the first K-shell filter and the object, generating a first set of image data,
- providing a second K-shell filter having a second K-shell energy,
- producing a second beam of X-ray radiation having a second mean energy being in the interval of 70-130% of the second K-shell energy,
- directing the second beam through the second K-shell filter, so that the intensity of the X-ray radiation transmitted by the second K-shell filter having an energy above the second K-shell energy is less than 20% of the total X-ray radiation transmitted by the second K-shell filter, and further through the object along a second path similar to the first path,
- detecting X-ray radiation transmitted through the second K-shell filter and the object,
- from the detected X-ray radiation transmitted through the second K-shell filter and the object, generating a second set of image data,
- from the first and second sets of image data, generating an image of the object.

16. A method according to claim 15, wherein at least three K-shell filters are provided and additionally comprising the

step of selecting from the at least three K-shell filters a K-shell filter to constitute the first K-shell filter and a K-shell filter to constitute the second K-shell filter.

17. A method according to claim 16, wherein the said selection is based on the weight of the object, the thickness thereof in the direction of the first and second beams or the length of circumference of the object.

18. A method according to claim 15, further comprising the steps of determining the intensity of the first and of the second beams transmitted by the first and second K-shell filters, respectively, using an X-ray radiation measuring means.

19. A method according to claim 15, wherein the step of generating the image comprises the step of removing low density structures and thereby enhancing higher density structures therein.

20. A method according to claim 15, wherein the step of generating the image comprises the step of removing higher density structures and thereby enhancing lower density structures therein.

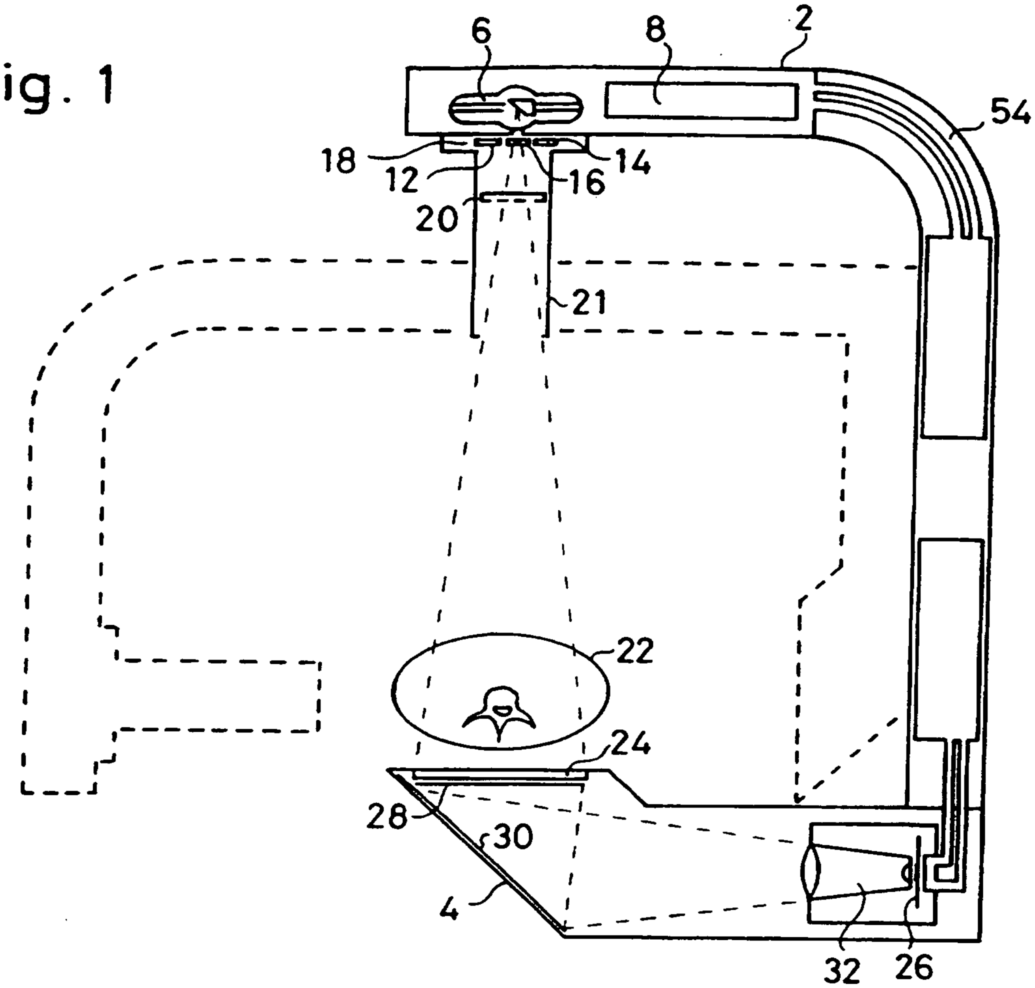
21. A method according to claim 15, further comprising the steps of determining parts of the image relating to bone structure of the object and of calculating, based on the image, parameters of the bones in the image.

22. A method according to claim 21, wherein the calculated parameters are chosen from the group of: Bone Mineral Density of individual bones in the image, a mean Bone Mineral Density of a group of bones in the image, Bone Mineral Content of individual bones in the image or a Bone Mineral Content for a group of bones in the image.

23. A method according to claim 15, further comprising the steps of:

- producing a third beam of X-ray radiation,
- directing the third beam through the object along a third path different from the first and the second paths,
- detecting X-ray radiation transmitted through the object,
- from the detected X-ray radiation transmitted through the object, generating a third set of image data, and wherein the step of generating the image comprises basing said generation on the first, second and third sets of image data.

Fig. 1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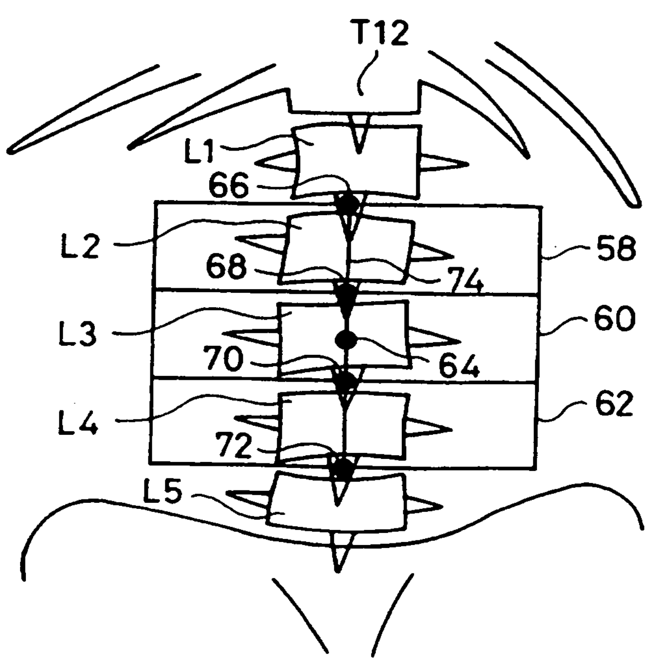
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L5

Fig. 2

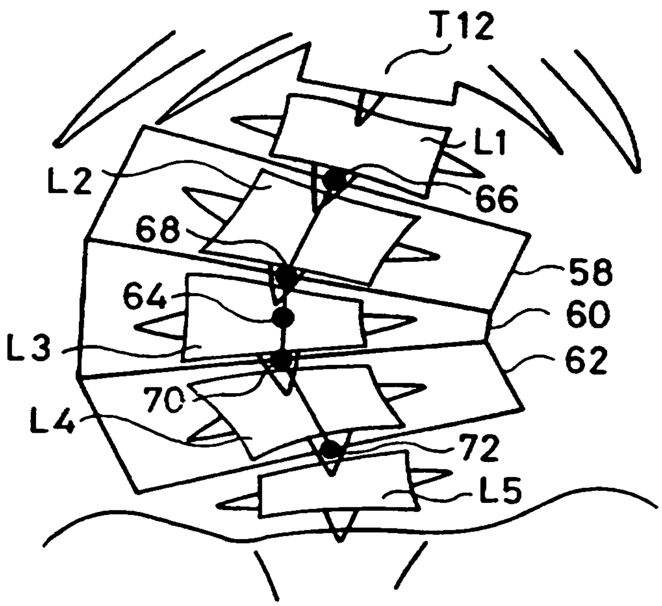

Fig. 3

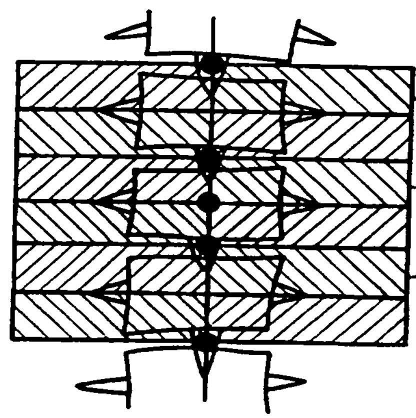

Fig. 4

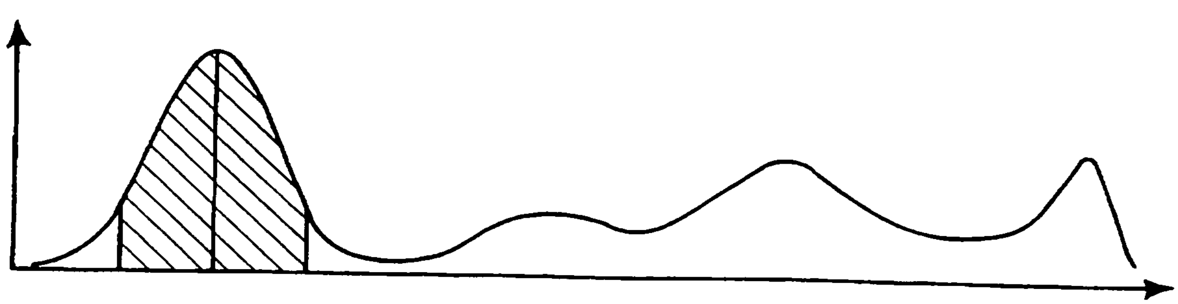

Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK 96/00556

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B6/00 A61B6/03

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 204 888 A (TAMEGAI & AL.) 20 April 1993 cited in the application see the whole document ---	1,2,4, 8-13, 15-22
Y	US 5 033 075 A (DEMONE & AL.) 16 July 1991 see the whole document ---	1,2,4, 8-13, 15-22
A	US 5 095 207 A (TONG) 10 March 1992 see column 11, line 1 - line 7 ---	3,5
A	US 3 679 902 A (HURST & AL.) 25 July 1972 see column 5, line 38 - line 66 ---	6,7
A	US 4 590 603 A (RELIHAN & AL.) 20 May 1986 see column 6, line 2 - line 6 --- -/--	6

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
26 May 1997	04.06.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lemercier, D

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/DK 96/00556

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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